

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N-0371]

Rami Elsharaiha; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Rami Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Elsharaiha was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Elsharaiha failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: *[Insert date of publication in the Federal Register.]*

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5640.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1994, the U.S. District Court for the District of Maryland entered judgment against Mr. Elsharaiha for one count of making false declarations before a grand jury, a Federal felony offense under 18 U.S.C. 1623.

DMB

Display Date	9/28/94
Publication Date	9/29/94
Certifier	J. W. Anderson

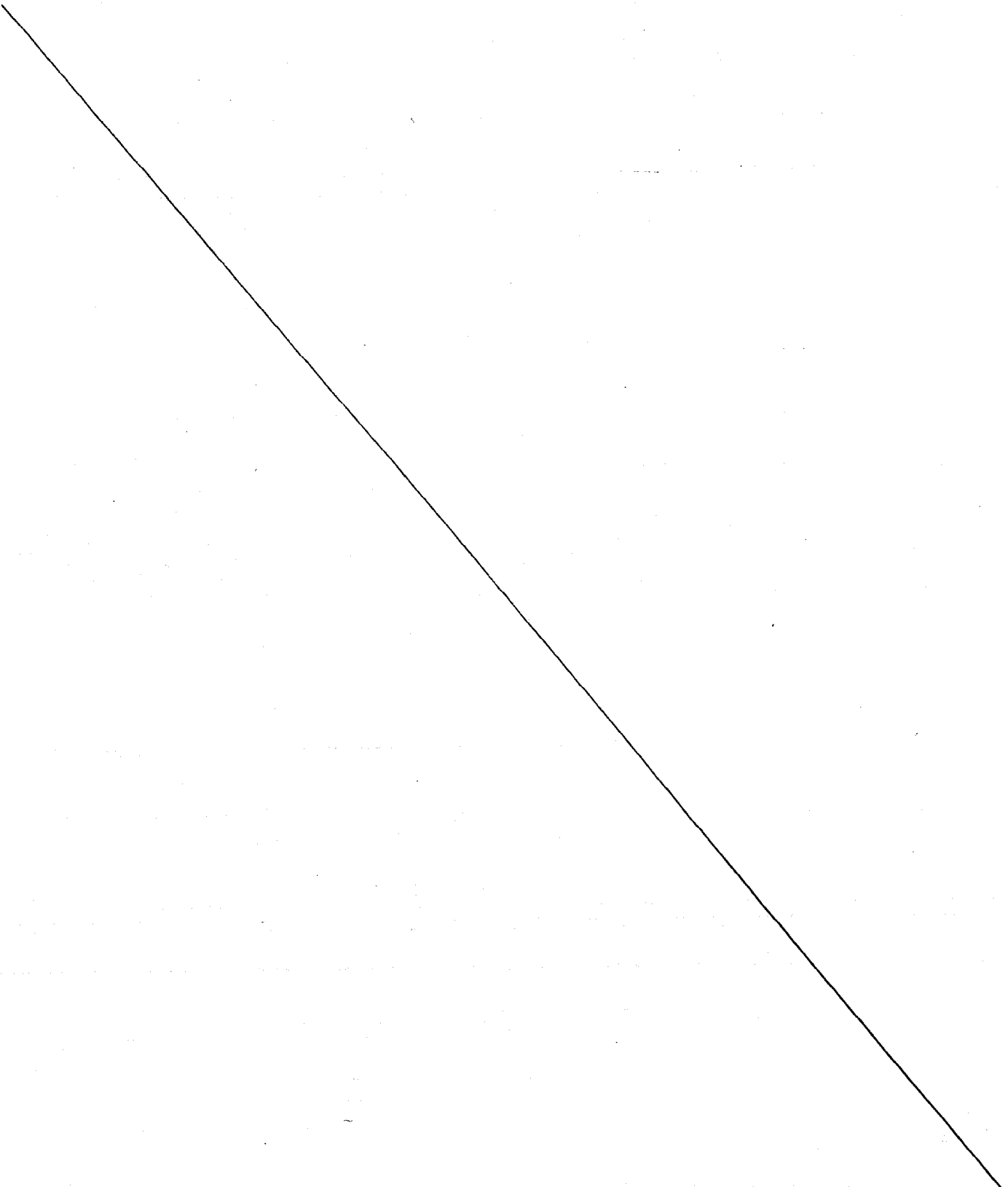
As a result of this conviction, FDA published in the **Federal Register** of January 19, 1999 (64 FR 2905), a notice proposing to permanently debar Mr. Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application, and offering him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Elsharaiha was provided 30 days to file objections and request a hearing. Mr. Elsharaiha did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director of the Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Rami Elsharaiha has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

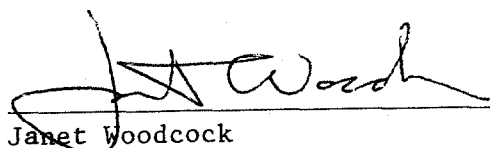
As a result of the foregoing finding, Mr. Rami Elsharaiha is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [*insert date of publication in the Federal Register*], (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Elsharaiha, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Elsharaiha, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Elsharaiha during his period of debarment.

Any application by Mr. Elsharaiha for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0371 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability



of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/11/00
September 11, 2000



Janet Woodcock
Director,
Center for Drug Evaluation and Research

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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